

510(k) Summary of Safety and Effectiveness

**PERI-LOC Ankle Fusion Bone Plates,
VLP 2.7mm Extra Large Percutaneous Calcaneus Plate
and Device Specific Instrument**

K120 667
PAGE 1 of 2

APR - 4 2012

Submitted By: Smith & Nephew, Inc.
Orthopaedics
1450 Brooks Road
Memphis, TN 38116

Date: March 2, 2012

Contact Person: David Henley, Regulatory Affairs Project Manager
Tel: (901) 399-6487 Fax: (901) 566-7079

Proprietary Name: PERI-LOC Ankle Fusion Bone Plates, VLP 2.7mm
Extra Large Percutaneous Calcaneus Plate and
Device Specific Instrument

Common Name: Bone Plates

Classification Name and Reference: 21 CFR 888.3030, Single/multiple component metallic
bone fixation appliances and accessories - Class II

Device Product Code and Panel Code: HRS / Orthopedics / 87

Device Description:

The subject devices are comprised of implantable, locking bone plates and a device specific instrument. All described implant components are manufactured from implant grade stainless steel material. The subject implant devices are available in the following sizes:

Device Type	Available Length
PERI-LOC 3.5mm Ankle Fusion Plates, Anterior Primary, LH/RH with Compression Slot, 3H	67mm
PERI-LOC 3.5mm Ankle Fusion Plates, Anterior Primary, LH/RH with Compression Slot, 5H	92mm
PERI-LOC 3.5mm Hindfoot Ankle Fusion Utility Plates, LH/RH with Compression Slot, 5H	104mm
VLP 2.7mm Percutaneous Calcaneus Plates, Extra Large, LH/RH	68mm

A new *device specific instrument* is also described in this Special 510(k) premarket notification in select sections and exhibits.

Intended Use:

The Smith & Nephew VLP FOOT Plating System can be used in adolescent (12-18 years) and transitional adolescent (18-21 years) subpopulations and adults, as well as patients with osteopenic

bone. The VLP FOOT Plating System is indicated for fracture fixation, reconstruction or arthrodesis of small bones, including those in the forefoot, midfoot and hindfoot.

The Smith & Nephew PERI-LOC Ankle Fusion Plating System can be used in adolescent (12-18 years) and transitional adolescent (18-21 years) subpopulations and adults, as well as patients with osteopenic bone. The PERI-LOC Ankle Fusion Plating System is indicated for ankle arthrodesis and fractures, including the distal tibia, talus and calcaneus.

Technological Characteristics:

The **PERI-LOC Ankle Fusion Plates** and **VLP Extra Large Percutaneous Calcaneus Plate** are very similar to legally marketed devices cleared under K110670. When compared to the predicates from K110670, the proposed devices share identical indications for use and intended use, are manufactured from identical materials, and incorporate identical or very similar technological design characteristics. The *device specific instrument* described in this premarket notification is also very similar to the predicate device specific instruments cleared under K110670.

Substantial Equivalence Information:

When compared to the predicate implant and device specific instrument devices cleared under the premarket notification listed below, substantial equivalence is based on similarities with regard to overall indications for use, material composition, and technological design characteristics.

- VLP FOOT Plating System and PERI-LOC Ankle Fusion Plating System – Locking Bone Plates and Screws and Device Specific Instruments – K110670

To further support a determination of substantial equivalence, a pre-clinical evaluation was conducted on the PERI-LOC Ankle Fusion Plates described in this premarket notification. Results were compared against previously cleared PERI-LOC Ankle Fusion Plate predicate devices described above and cleared under K110670.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room - WO66-G609
Silver Spring, MD 20993-0002

Smith & Nephew
% Mr. David Henley
Regulatory Affairs Project Manager
1450 Brooks Road
Memphis, TN 38116

APR - 4 2012

Re: K120667

Trade/Device Name: PERI-LOC Ankle Fusion Bone Plates, VLP 2.7mm
Extra Large Percutaneous Calcaneus Plate and Device Specific
Instrument

Regulation Number: 21 CFR 888.3030

Regulation Name: Single/multiple component metallic bone fixation appliances and
accessories

Regulatory Class: II

Product Code: HRS

Dated: March 2, 2012

Received: March 5, 2012

Dear Mr. Henley:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,



for Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

**Premarket Notification
Indications for Use Statement**

510(k) Number (if known): K120667

Device Name: **PERI-LOC Ankle Fusion Plates and VLP Extra Large Percutaneous Calcaneus Plate**

Indications for Use:

The Smith & Nephew PERI-LOC Ankle Fusion Plating System can be used in adolescent (12-18 years) and transitional adolescent (18-21 years) subpopulations and adults, as well as patients with osteopenic bone. The PERI-LOC Ankle Fusion Plating System is indicated for ankle arthrodesis and fractures, including the distal tibia, talus and calcaneus.

The Smith & Nephew VLP FOOT Plating System can be used in adolescent (12-18 years) and transitional adolescent (18-21 years) subpopulations and adults, as well as patients with osteopenic bone. The VLP FOOT Plating System is indicated for fracture fixation, reconstruction or arthrodesis of small bones, including those in the forefoot, midfoot and hindfoot.

PERI-LOC Ankle Fusion Bone Plates and the VLP Extra Large Percutaneous Calcaneus Plate are for single use only.

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-the-Counter Use _____
(Optional Format 1-2-96)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)


(Division Sign-Off)

Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K120667